FEDERAL ADMINISTRATIVE SANCTIONS

HCCA ENFORCEMENT COMPLIANCE CONFERENCE

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TOPICS

- CMS ADMINISTRATIVE REMEDIES
- OIG ADMINISTRATIVE REMEDIES
  - CIVIL MONETARY PENALTIES (CMP) LAW
  - EXCLUSION

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CMS ADMINISTRATIVE REMEDIES

- ENROLLMENT DENIAL
- REVOCATION
- DEACTIVATION
- OVERPAYMENT RECOVERY
- PAYMENT SUSPENSION

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CMS CENTER FOR PROGRAM INTEGRITY

- CMS'S FOCAL POINT FOR NATIONAL AND STATE-WIDE MEDICARE/MEDICAID/CHIP INTEGRITY FRAUD ABUSE ISSUES
- PROMOTES THE INTEGRITY OF MEDICARE/MEDICAID/CHIP THROUGH:
  - PROVIDER/CONTRACTOR AUDITS AND POLICY REVIEWS
  - IDENTIFICATION AND MONITORING OF PROGRAM VULNERABILITIES
  - PROVIDING SUPPORT AND ASSISTANCE TO STATES
- RECOMMENDS MODIFICATIONS TO PROGRAMS AND OPERATIONS AND DEVELOPS AND ADVANCES LEGISLATION
- OVERSEES ALL CMS PI-RELATED INTERACTIONS AND COLLABORATION WITH KEY STAKEHOLDERS (DOJ, OIG, STATES)
- DEVELOPS AND IMPLEMENTS A COMPREHENSIVE STRATEGIC PLAN, OBJECTIVES AND MEASURES TO CARRY OUT CMS'S MEDICARE/MEDICAID/CHIP PROGRAM INTEGRITY MISSION AND GOALS, AND ENSURE PROGRAM VULNERABILITIES ARE IDENTIFIED AND RESOLVED

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REVOCATION

- CMS HAS 20 REGULATORY BASES UPON WHICH TO REVOKE A PROVIDER'S MEDICARE FFS BILLING PRIVILEGES. EXAMPLES INCLUDE:
  - NON-COMPLIANCE WITH MEDICARE ENROLLMENT REQUIREMENTS
  - CERTAIN FELONY CONVICTIONS
  - SUBMISSION OF FALSE OR MISLEADING APPLICATION INFORMATION
  - DETERMINATION THAT THE PROVIDER IS NON-OPERATIONAL
  - ABUSE OF BILLING PRIVILEGES
  - FAILURE TO COMPLY WITH ENROLLMENT REPORTING REQUIREMENTS
  - TERMINATION OF MEDICAID BILLING PRIVILEGES

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RE-ENROLLMENT BAR / CORRECTIVE ACTION PLANS

- REVOCATION – BAR ON RE-ENROLLING IN MEDICARE FOR ONE TO 10 YEARS
- IF SECOND REVOCATION – BAR ON RE-ENROLLMENT IS UP TO 20 YEARS
- UP TO THREE MORE YEARS ADDED TO RE-ENROLLMENT BAR IF CMS DETERMINES PROVIDER IS ATTEMPTING TO CIRCUMVENT ITS EXISTING RE-ENROLLMENT BAR BY ENROLLING IN MEDICARE UNDER A DIFFERENT NAME, NUMERICAL IDENTIFIER, OR BUSINESS IDENTITY.
- IF REVOCATION BASED ON NON-COMPLIANCE WITH MEDICARE ENROLLMENT REQUIREMENTS, A PROVIDER MAY SUBMIT A CORRECTIVE ACTION PLAN (CAP) FOR CMS'S CONSIDERATION.
  - IF CMS APPROVES THE CAP, REVOCATION REVERSED
  - IF CMS DENIES THE CAP, THE PROVIDER CANNOT APPEAL CAP DECISION
    - BUT MAY CONTINUE APPEAL OF REVOCATION DETERMINATION

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REVOCATION APPEALS

- A PROVIDER MAY APPEAL A REVOCATION DETERMINATION BY REQUESTING RECONSIDERATION BEFORE A CMS HEARING OFFICER.
- THE RECONSIDERATION IS AN INDEPENDENT REVIEW CONDUCTED BY AN OFFICER NOT INVOLVED IN THE INITIAL DETERMINATION.
- IF THE PROVIDER IS DISSATISFIED WITH THE RECONSIDERATION DECISION, THE PROVIDER MAY REQUEST A HEARING BEFORE AN HHS ADMINISTRATIVE LAW JUDGE (ALJ) WITHIN THE DEPARTMENTAL APPEALS BOARD (DAB).
- THEREAFTER, A PROVIDER MAY SEEK DAB REVIEW AND THEN JUDICIAL REVIEW.

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DEACTIVATION

- CMS MAY DEACTIVATE A PROVIDER'S BILLING PRIVILEGES BASED ON:
  - NO SUBMISSION OF MEDICARE CLAIMS FOR 12 CONSECUTIVE CALENDAR MONTHS
  - FAILURE TO REPORT A CHANGE IN INFORMATION (E.G., PRACTICE LOCATION, BILLING SERVICES, OR OWNERSHIP)
  - FAILURE TO RESPOND TO A CMS NOTICE TO SUBMIT OR CERTIFY ENROLLMENT INFORMATION.
- NO RE-ENROLLMENT BAR
- IN MOST CASES, A PROVIDER CAN REACTIVATE ITS MEDICARE ENROLLMENT AT ANY TIME BY SUBMITTING A NEW ENROLLMENT APPLICATION OR RECERTIFYING THE INFORMATION ON FILE

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AUTOMATED ACTIONS IN MEDICARE - EDITS

- AUTOMATED ACTIONS PREVENT IMPROPER PAYMENTS TO PROVIDERS
- EDITS, OR SETS OF INSTRUCTIONS, CODED INTO A CLAIMS PROCESSING SYSTEM TO IDENTIFY AND AUTOMATICALLY DENY OR REJECT ALL OR PART OF A CLAIM EXHIBITING SPECIFIC ERRORS OR INCONSISTENCY WITH MEDICARE POLICY.
- CMS CALCULATES AUTOMATED ACTION SAVINGS FROM THE FOLLOWING EDITS OF MEDICARE FFS CLAIMS:
  - NATIONAL CORRECT CODING INITIATIVE (NCCI) PROCEDURE-TO-PROCEDURE (PTP) EDITS
  - NCCI MEDICALLY UNLIKELY EDITS (MUES)
  - ORDERING AND REFERRING (O&R) EDITS
  - FRAUD PREVENTION SYSTEM (FPS) EDITS
  - MEDICARE ADMINISTRATIVE CONTRACTOR (MAC) AUTOMATED MEDICAL REVIEW EDITS
  - UNIFIED PROGRAM INTEGRITY CONTRACTOR (UPIC) AUTOMATED EDITS

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OVERPAYMENT RECOVERY

- DEMAND LETTER FROM MAC
  - INFORMATION ABOUT OVERPAYMENT, PROCESS, APPEAL RIGHTS
- RESPONSE FROM PROVIDER
  - PAY OR REQUEST RECOUPMENT
  - EXTENDED REPAYMENT SCHEDULE (ERS)
  - REBUTTAL TO MAC
  - APPEAL

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OVERPAYMENT APPEAL

- MEDICARE PART A AND PART B HAS *5* APPEAL LEVELS:
- 1) REDETERMINATION OCCURS AFTER THE INITIAL PART A AND PART B CLAIMS DETERMINATION. A MAC RE-EXAMINES THE CLAIM AND SUPPORTING DOCUMENTATION. A MAC EMPLOYEE NOT INVOLVED IN THE INITIAL DETERMINATION MAKES THE REDETERMINATION.
- 2) RECONSIDERATION BY A QUALIFIED INDEPENDENT CONTRACTOR (QIC)
- 3) HEARING BY AN ADMINISTRATIVE LAW JUDGE (ALJ) OR REVIEW BY AN ATTORNEY ADJUDICATOR AT THE OFFICE OF MEDICARE HEARINGS AND APPEALS (OMHA)
- 4) REVIEW BY THE MEDICARE APPEALS COUNCIL
- 5) JUDICIAL REVIEW IN U.S. DISTRICT COURT

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PAYMENT SUSPENSION

- MEDICARE - 42 CFR §§ 405.370-405.379
- MEDICAID - 42 CFR § 455.23
- WITHHOLDING OF PAYMENT OF AN APPROVED AMOUNT
  - BEFORE A DETERMINATION OF THE AMOUNT OF THE OVERPAYMENT, OR
  - UNTIL THE RESOLUTION OF AN INVESTIGATION OF A CREDIBLE ALLEGATION OF FRAUD

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CREDIBLE ALLEGATION OF FRAUD

- ALLEGATION FROM ANY SOURCE, INCLUDING BUT NOT LIMITED TO:
  - FRAUD HOTLINE TIPS VERIFIED BY FURTHER EVIDENCE
  - DATA MINING
  - PROVIDER AUDITS
  - FALSE CLAIMS ACT CASES
  - LAW ENFORCEMENT INVESTIGATIONS
- CREDIBLE = INDICIA OF RELIABILITY

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PAYMENT SUSPENSION - CREDIBLE ALLEGATION OF FRAUD

- **MEDICARE** – CMS/CONTRACTOR **MAY** SUSPEND BASED ON ALLEGATION
  - MAY BE IN WHOLE OR IN PART
  - AFTER CONSULTATION WITH OIG (AND, IF APPROPRIATE, DOJ)
  - UNLESS THERE IS GOOD CAUSE NOT TO SUSPEND
- **MEDICAID** - THE STATE MEDICAID AGENCY **MUST** SUSPEND **ALL** MEDICAID PAYMENTS TO A PROVIDER AFTER THE AGENCY DETERMINES THERE IS A CREDIBLE ALLEGATION OF FRAUD FOR WHICH AN INVESTIGATION IS PENDING UNDER THE MEDICAID PROGRAM
  - UNLESS THE AGENCY HAS GOOD CAUSE TO NOT SUSPEND PAYMENTS OR TO SUSPEND PAYMENT ONLY IN PART

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PAYMENT SUSPENSION PROCESS

- NOTICE TO PROVIDER
  - MULTIPLE EXCEPTIONS, INCLUDING INVESTIGATION OF CREDIBLE ALLEGATION OF FRAUD
- OPPORTUNITY FOR REBUTTAL TO CONTRACTOR
- CONTRACTOR DETERMINATION ON REBUTTAL NOT APPEALABLE
- OVERPAYMENT – 180 DAYS (PLUS POSSIBLE EXTENSION OF 180 DAYS)
- CREDIBLE ALLEGATION OF FRAUD – UNTIL RESOLUTION OF INVESTIGATION
- SUSPENDED FUNDS FIRST APPLIED TO ELIMINATE OVERPAYMENTS AND OTHER OBLIGATIONS TO CMS OR HHS

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CIVIL MONETARY PENALTIES LAW (CMPL)

- ADMINISTRATIVE FRAUD REMEDY
  - SECTION 1128A OF THE SOCIAL SECURITY ACT
    - CODIFIED AT 42 U.S.C. § 1320A-7A
    - REGULATIONS: 42 C.F.R. § 1003

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CMPL AUTHORITIES

- MORE THAN 40 CMP AUTHORITIES PROVIDE GROUNDS FOR ENFORCEMENT ACTIONS, INCLUDING:
  - FALSE OR FRAUDULENT CLAIMS
  - KICKBACKS
  - EMPLOYING OR CONTRACTING WITH EXCLUDED PERSON
  - OWNERSHIP, CONTROL, OR MANAGEMENT WHILE EXCLUDED
  - ORDERING OR PRESCRIBING WHILE EXCLUDED
  - KNOWING FALSE STATEMENT ON APPLICATION, BID OR CONTRACT TO PARTICIPATE OR ENROLL
  - KNOWING RETENTION OF OVERPAYMENT
  - GRANT AND CONTRACT FRAUD

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CMPL REMEDIES

- PENALTIES
  - UP TO $20,000 - $100,000 PER VIOLATION
  - AMOUNT VARIES BY TYPE OF VIOLATION
  - PENALTIES UPDATED ANNUALLY FOR INFLATION, 45 CFR PART 102
- ASSESSMENT
  - UP TO 3 TIMES AMOUNT CLAIMED
- EXCLUSION
  - FROM MEDICARE, MEDICAID, AND ALL OTHER FEDERAL HEALTH CARE PROGRAMS

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OCIG ENFORCEMENT ACTIONS

- TELEMEDICINE FRAUD
  - CONDUCT: PROVIDERS RECEIVED KICKBACKS IN EXCHANGE FOR ORDERING MEDICALLY UNNECESSARY DURABLE MEDICAL EQUIPMENT, GENETIC TESTING, AND PRESCRIPTION MEDICATIONS.
  - RESULTS:
    - CRAIG COPELAND, MD – 10-YEAR EXCLUSION
    - THOMAS BYRNE, MD – $223,502
    - VI DANG, MD – $132,078
    - MORGAN WOOD, MD – $150,000

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ADMINISTRATIVE PROCESS

- CASES ARE DEVELOPED BY OCIG INTERNALLY, OR ARE REFERRED TO OCIG BY OTHER OIG COMPONENTS OR OTHER GOVERNMENTAL ENTITIES (MFCUS, USAOS, MACS, ETC.)
- OCIG CONDUCTS ADDITIONAL INVESTIGATION, IF NECESSARY (CMPL SUBPOENA POWER FOR DOCUMENTS/TESTIMONY)
- WHEN INVESTIGATION IS COMPLETE, IF SETTLEMENT IS NOT REACHED, OCIG ISSUES A "DEMAND LETTER" TO PROVIDER, OUTLINING ALLEGATIONS AND IMPOSING PENALTIES, ASSESSMENT, AND/OR EXCLUSION
- PROVIDER CAN APPEAL TO AN ADMINISTRATIVE LAW JUDGE

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ADMINISTRATIVE ADJUDICATION

ADMINISTRATIVE LAW JUDGE HEARING

- BURDEN OF PROOF
  - PREPONDERANCE OF THE EVIDENCE (SAME AS CIVIL)
- STATUTE OF LIMITATIONS
  - GENERALLY, 6 YEARS (SAME AS CIVIL)
- INTENT
  - GENERALLY, "KNEW OR SHOULD HAVE KNOWN"
  - DELIBERATE IGNORANCE OR RECKLESS DISREGARD
- HEARSAY IS ADMISSIBLE: FRE SERVE AS A GUIDELINE

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EXCLUSION – WHAT IS IT?

- ONCE EXCLUDED, AN INDIVIDUAL OR ENTITY IS PROHIBITED FROM PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS
  - DOES NOT AFFECT A PERSON'S RIGHT TO RECEIVE PROGRAM BENEFITS
- EXCLUSION IS REMEDIAL
- NO FEDERAL HEALTH CARE PROGRAM PAYMENT MAY BE MADE FOR ITEMS OR SERVICES:
  - FURNISHED BY AN EXCLUDED INDIVIDUAL OR ENTITY
  - DIRECTED OR PRESCRIBED BY AN EXCLUDED INDIVIDUAL, WHERE THE PERSON FURNISHING THE ITEM OR SERVICE KNEW OR HAD REASON TO KNOW OF THE EXCLUSION
- 2 TYPES OF PROVIDERS MAY BE EXCLUDED:
  - DIRECT PROVIDERS (*E.G.,* DOCTORS, NURSES, HOSPITALS) AND
  - INDIRECT PROVIDERS (*E.G.,* DRUG MANUFACTURERS, DEVICE MANUFACTURERS)

•**OVER 75,000 INDIVIDUALS AND ENTITIES CURRENTLY EXCLUDED**

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MANDATORY EXCLUSIONS

- SECTION 1128(A) OF THE SOCIAL SECURITY ACT (SSA)
  - 4 MANDATORY AUTHORITIES BASED ON CONVICTIONS FOR:
    - (1) CONVICTION OF PROGRAM-RELATED CRIMES (MEDICARE/MEDICAID FRAUD)
    - (2) CONVICTION RELATED TO PATIENT ABUSE/NEGLECT
    - (3) FELONY CONVICTION RELATED TO HEALTH CARE FRAUD
    - (4) FELONY CONVICTION RELATING TO CONTROLLED SUBSTANCE
  - "RELATED TO" STANDARD HAS BEEN DEFINED VERY BROADLY: COMMONSENSE CONNECTION OR NEXUS.
  - CONVICTION IS BROADLY DEFINED IN SSA SECTION 1128(I)
  - MINIMUM EXCLUSION TERM OF 5 YEARS
    - OIG MAY INCREASE LENGTH OF EXCLUSION BASED ON STATUTORY AND REGULATORY FACTORS (AGGRAVATING AND MITIGATING)

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Abuse and Neglect Example: Donna C. Pagan

- Certified nursing assistant (CNA) assigned to care for beneficiary.
- Another CNA called for assistance because beneficiary had fallen due to improper use of a lift by the CNA without assistance of another person, as required.
- Petitioner delayed calling for emergency assistance and agreed to falsely report that she was assisting CNA at the time.
- The beneficiary died at the hospital two hours after the incident.
- Original charge: Felony complaint of falsifying business records with intent to defraud and conceal another crime.
- Accepted reduced charge: Falsifying business records.
- Exclusion under 1128(a)(2) was upheld on appeal to an ALJ.

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RELATED TO FRAUD EXAMPLE: PURDUE PHARMA EXECS

- PURDUE PHARMA – MANUFACTURED OXYCONTIN
- COMPANY CHARGED WITH FELONY CRIMINAL MISBRANDING A DRUG WITH INTENT TO DEFRAUD OR MISLEAD; GUILTY PLEA, $600 MILLION SANCTIONS;
- 3 EXECS CHARGED WITH MISDEMEANOR MISBRANDING AS "RESPONSIBLE CORPORATE OFFICERS" ("STRICT LIABILITY" CRIME);
- EXCLUDED UNDER 42 USC §1320A-7(B)(1)(A): MISDEMEANOR "RELATING TO FRAUD"
- UPHELD BY ALJ, DEPARTMENTAL APPEALS BOARD, USDC, DC CIRCUIT COA
- DC COA: "'RELATING TO' MUST DENOTE A FACTUAL RELATIONSHIP BETWEEN THE CONDUCT UNDERLYING THE MISDEMEANOR AND THE CONDUCT UNDERLYING A 'FRAUD.'"

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PERMISSIVE EXCLUSIONS

- SSA SECTION 1128(B)
  - 17 AUTHORITIES IN SECTION 1128 (MORE ELSEWHERE), MOST ARE DERIVATIVE AND INCLUDE:
    - MISDEMEANOR HEALTH CARE (NON-MEDICARE/MEDICAID) FRAUD AND CONTROLLED SUBSTANCES CONVICTIONS
    - OBSTRUCTION OF INVESTIGATION/AUDIT
    - LICENSE REVOCATION OR SUSPENSION
    - FAILURE TO SUPPLY PAYMENT INFORMATION OR GRANT IMMEDIATE ACCESS
    - KNOWING FALSE STATEMENTS OR MISREPRESENTATIONS ON ENROLLMENT APPLICATIONS
- TERM OF PERMISSIVE EXCLUSION VARIES BASED ON THE AUTHORITY
  - MOST AUTHORITIES HAVE A BASE PERIOD OF 3 YEARS
  - ADJUSTMENTS TO TERM BASED ON AGGRAVATING AND MITIGATING FACTORS

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AFFIRMATIVE VS. DERIVATIVE EXCLUSIONS

1) **DERIVATIVE = BASED ON ACTIONS OF ANOTHER AGENCY:**
   - CONVICTION FROM A COURT
   - REVOCATION/SUSPENSION OF A HEALTH CARE PROFESSIONAL LICENSE BY STATE LICENSING AGENCY
   - EXCLUSION FROM STATE MEDICAID PROGRAM
2) **AFFIRMATIVE = MUST BE PROVED BY OIG IN AN ADMINISTRATIVE TRIBUNAL**
   - FURNISHING SERVICES OF A QUALITY WHICH FAILS TO MEET PROFESSIONALLY RECOGNIZED STANDARDS OF CARE
   - FRAUD, KICKBACKS, AND OTHER PROHIBITED ACTIVITIES
   - EXCLUSION UNDER THE CMPL

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PERMISSIVE 1128(B)(7) EXCLUSIONS

- FRAUD, KICKBACKS, AND OTHER PROHIBITED ACTIVITIES
- 62 FED. REG. 67392 (DEC. 24, 1997), SUPERSEDED AND REPLACED BY NEW CRITERIA FOR IMPLEMENTING SECTION 1128(B)(7) EXCLUSION AUTHORITY, PUBLISHED ON APRIL 18, 2016:
- HTTPS://OIG.HHS.GOV/EXCLUSIONS/FILES/1128B7EXCLUSION-CRITERIA.PDF
- UPDATED CRITERIA EXPLAINS:
  - EVALUATING RISK TO FEDERAL HEALTH CARE PROGRAMS
  - ASSESSING WHETHER TO IMPOSE EXCLUSION UNDER SECTION 1128(B)(7)
- BEGINS WITH THE PRESUMPTION THAT EXCLUSION SHOULD BE IMPOSED

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PERMISSIVE 1128(B)(7) EXCLUSION FACTORS – OIG CONSIDERATIONS

- NATURE AND CIRCUMSTANCES OF CONDUCT
  - ADVERSE IMPACT ON INDIVIDUALS
  - FINANCIAL LOSS
  - CONDUCT AS PART OF PATTERN
  - CONDUCT OVER SUBSTANTIAL PERIOD OF TIME
  - LEADERSHIP ROLE
  - HISTORY OF PRIOR PAST CONDUCT
- CONDUCT DURING INVESTIGATION
  - OBSTRUCTION OF INVESTIGATION
  - CONCEALMENT OF CONDUCT
  - INTERNAL INVESTIGATION
  - COOPERATION
  - RESOLUTION

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PERMISSIVE 1128(B)(7) EXCLUSION FACTORS

- SIGNIFICANT AMELIORATIVE EFFORTS
  - SIGNIFICANT CHANGES IN THE ENTITY
    - DISCIPLINARY ACTIONS AGAINST RESPONSIBLE ACTORS
    - DEVOTION OF SIGNIFICANT RESOURCES TO COMPLIANCE
    - SALE OF ENTITY TO THIRD PARTY
- HISTORY OF COMPLIANCE
  - HISTORY OF SIGNIFICANT SELF-DISCLOSURES TO OIG, CMS, CMS CONTRACTORS
  - EXISTENCE OF COMPLIANCE PROGRAM DOES NOT AFFECT RISK ASSESSMENT
  - ABSENCE OF COMPLIANCE PROGRAM INDICATES HIGHER RISK

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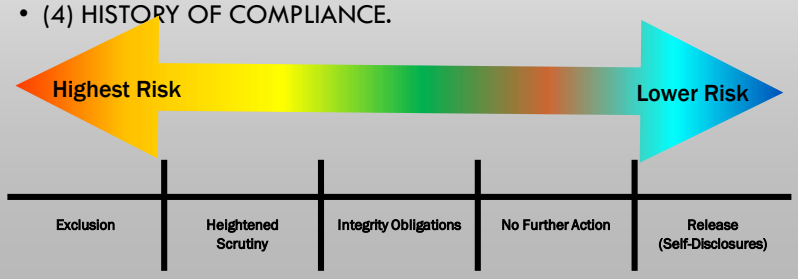
RISK SPECTRUM

PROVIDES A COMPLIANCE "RISK SPECTRUM" FROM HIGH TO LOW RISK BASED ON:

- (1) NATURE AND CIRCUMSTANCES OF CONDUCT;
- (2) CONDUCT DURING INVESTIGATION;
- (3) SIGNIFICANT AMELIORATIVE EFFORTS; AND
- (4) HISTORY OF COMPLIANCE.



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APPEALS OF OIG EXCLUSIONS: 42 C.F.R. PART 1005

- HEARING IS BEFORE THE HHS DEPARTMENTAL APPEALS BOARD (DAB), ADMINISTRATIVE LAW JUDGE (ALJ)
- ALJ REVIEWS WHETHER OIG HAD A LEGAL BASIS FOR ITS ACTIONS AND REASONABLENESS OF LENGTH OF EXCLUSION
- APPEAL TO APPELLATE PANEL OF THE DAB, THEN TO US DISTRICT COURT
- BURDEN OF PROOF: PREPONDERANCE OF THE EVIDENCE

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QUESTIONS?

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